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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,323	07/11/2001	Edward M. De Robertis	510015-261	8375

7590 08/21/2003
Attention: Charles Berman
OPPENHEIMER WOLFF & DONNELLY
2029 Century Park East, 38th Floor
Los Angeles, CA 90067-3024

EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/21/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,323	DE ROBERTIS ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The preliminary amendments filed July 11, 2001 (Paper Nos. 1½ and 2½) have been entered. Claims 9-11 are pending and being examined.

5 This application discloses and claims only subject matter disclosed in prior Application No. 08/878474, filed June 6, 1997, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

10

It is noted that the present application claims benefit to intermediate nonprovisional application 09/552,988 that is directly claiming the benefit of the provisional application 60/020,150. Both the present application and the intermediate nonprovisional application were filed more that 12 months from the filing date of the provisional application. A nonprovisional
15 application that directly claims the benefit of a provisional application under 35 U.S.C. 119(e)
must be filed within 12 months from the filing date of the provisional application. If a benefit claim to a provisional application is submitted without an indication that an intermediate application directly claims the benefit of the provisional application and the instant nonprovisional application is not filed within the 12 month period or the relationship between
20 each nonprovisional application is not indicated, the Office will not recognize such benefit claim and will not include the benefit claim on the filing receipt. Therefore, a petition under 37 CFR 1.78(a) and the surcharge set forth in 37 CFR 1.17(t) will be required if the intermediate

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application and the relationship of each nonprovisional application are not indicated within the period set forth in 37 CFR 1.78(a). Even if the Office has recognized a benefit claim by entering it into the Office's database and including it on applicant's filing receipt, the benefit claim is not a proper benefit claim under 35 U.S.C. 119(e) or 35 U.S.C. 120 and 37 CFR 1.78 unless the
5 reference is included in an ADS or in the first sentence of the specification and all other requirements are met. Accordingly, the benefit of the filing date of the provisional application 60/020,150 is denied.

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed
10 application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent
15 application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after
20 November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant

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• application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

20 The disclosure is objected to because of the following informalities: Priority claims under 35 U.S.C. 119(e) and benefit claims under 35 U.S.C. 120, 121 or 365(c) should appear as the first sentence of the specification following the title, preferably as a separate paragraph

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unless it appears in an application data sheet. It is acknowledged that the present disclosure contains a priority claim under 35 U.S.C. 119(e) and a benefit claim under 35 U.S.C. 120 but they do not appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet.

5 Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by DeRobertis (n8).

15 This rejection is being made because the benefit of the filing date of the provisional application 60/020,150 is denied.

DeRobertis discloses the human frzb-1 protein and nucleotide sequences (page 14, full

paragraph 1; figures 9 and 10), a mammalian or viral vector comprising the nucleotide sequence

(page 16, full paragraph 1), and a soluble form of the protein (page 4, full paragraph 1). The

20 amino acid sequence of human frzb-1 is identical to SEQ ID NO: 9 of the present application, as indicated below, and SEQ ID NO: 9 of the present application is expressed from SEQ ID NO: 10 of the present application.

25 AAW41254
ID AAW41254 standard; Protein; 325 AA.
XX
AC AAW41254;
XX
DT 09-JUL-1998 (first entry)
30 XX
DE Human "frazzled" frzb-1.
XX

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KW Growth factor; frazzled; frzb-1; Wnt5 antagonist; human;
 KW tumour suppressor; cancer.
 XX
 OS Homo sapiens.
 XX
 PN WO9748275-A1.
 XX
 PD 24-DEC-1997.
 XX
 PF 19-JUN-1997; 97WO-US10942.
 XX
 PR 18-JUN-1997; 97US-0878474.
 PR 20-JUN-1996; 96US-0020150.
 XX
 PA (REGC) UNIV CALIFORNIA.
 XX
 PI Bouwmeester T, De Robertis EM;
 XX
 DR WPI; 1998-062760/06.
 DR N-PSDB; AAV14017.
 XX
 PT New isolated growth factors - with neurotrophic, growth or
 differentiation factor activity, tumour growth suppressor activity
 or mesoderm differentiation activity
 XX
 PS Claim 6; Fig 9; 48pp; English.
 XX
 CC The present sequence is the human growth factor protein
 "frazzled" frzb-1. frzb-1 is an antagonist of Wnt5 in vivo, and
 thus is believed to find utility as a tumour suppressor gene,
 since overexpressed Wnt proteins cause cancer. Frzb-1 may also be a
 useful vehicle for solubilisation and therapeutic delivery of
 complexed Wnt proteins.
 XX
 SQ Sequence 325 AA;
 Query Match 100.0%; Score 1738; DB 19; Length 325;
 Best Local Similarity 100.0%; Pred. No. 2e-167;
 Matches 325; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 QY 1 M VCGSPGGM L L L R A G L L A A L C L L R V P G A R A A A C E P V R I P L C K S L P W N M T K M P N H L H S 60
 Db 1 M VCGSPGGM L L L R A G L L A A L C L L R V P G A R A A A C E P V R I P L C K S L P W N M T K M P N H L H S 60
 QY 61 T Q A N A I L A I E Q F E G L L G T H C S P D L L F F L C A M Y A P I C T I D F Q H E P I K P C K S V C E R A R Q G C E 120
 Db 61 T Q A N A I L A I E Q F E G L L G T H C S P D L L F F L C A M Y A P I C T I D F Q H E P I K P C K S V C E R A R Q G C E 120
 QY 121 P I L I K Y R H S W P E N L A C E E L P V Y D R G V C I S P E A I V T A D G A D F P M D S S N G N C R G A S S E R C K C 180
 Db 121 P I L I K Y R H S W P E N L A C E E L P V Y D R G V C I S P E A I V T A D G A D F P M D S S N G N C R G A S S E R C K C 180
 QY 181 K P I R A T Q K T Y F R N N Y N Y V I R A K V K E I K T C H D V T A V V E V K E I L K S S L V N I P R D T V N L Y T S 240
 Db 181 K P I R A T Q K T Y F R N N Y N Y V I R A K V K E I K T C H D V T A V V E V K E I L K S S L V N I P R D T V N L Y T S 240
 QY 241 S G C L C P P L A N V N E E Y I I M G Y E D E E R S R L L L V E G S I A E K W K D R L G K K V K R W D M K L R H L G L S K 300
 Db 241 S G C L C P P L A N V N E E Y I I M G Y E D E E R S R L L L V E G S I A E K W K D R L G K K V K R W D M K L R H L G L S K 300
 QY 301 S D S S N S D S T Q S Q S G R N S N P R Q A R N 325
 Db 301 S D S S N S D S T Q S Q S G R N S N P R Q A R N 325

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite over the recitation of "the protein being expressible from

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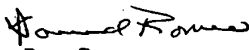
- SEQ ID NO: 10" (claim 9) and "expressible in soluble form" (claim 10). According to Wang (1997, cited by Applicants), release of soluble frzb protein may be dependent upon on proteolytic processing, which may vary with the cell or tissue type (page 762, left column, full paragraph 2). Leyns (1997, cited by Applicants) provides indirect evidence that the COOH end of Frzb-1 is
5 cleaved proteolytically (paragraph bridging pages 749-750). It is unclear which protein is being expressed and which soluble form is intended. The metes and bounds are not clearly set forth.

Conclusion

No claims are allowable.

- 10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.
- 15 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.
- IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:
- BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307
- 20 IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.
- CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).
- FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.
- 25 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.
-

30


DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
AUGUST 20, 2003